IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

DONALD PRUITT,

Plaintiff,

vs. No. CIV 94-1123JP/LCS

ABBOTT LABORATORIES,

Defendant.

**FINDINGS OF FACT AND CONCLUSIONS OF LAW**

**Findings of Fact**

1. Plaintiff Donald Pruitt is a resident of New Mexico; Defendant Abbott Laboratories is an Illinois corporation with its principal place of business in Illinois.
2. Plaintiff was born September 7, 1931.
3. On October 28, 1993, David C. Faragher, MD, a specialist in hematology-oncology, who practiced medicine in Colorado, diagnosed Plaintiff has having hemachromatosis, a medical illness in the nature of an iron-storage disorder resulting from intestines absorbing excessively large amounts of iron.
4. Also, on October 28, 1993, Dr. Faragher performed a neurological examination on the Plaintiff that was normal. By education, training and experience, Dr. Faragher was competent to perform the neurologic examination on October 28, 1993.
5. Dr. Faragher recommended that Plaintiff's condition of hemachromatosis be treated by periodic therapeutic phlebotomies.
6. Elyse Bowman, an oncology-certified registered nurse who worked in the office of Dr. Faragher, performed therapeutic phlebotomies on Plaintiff in Dr. Faragher's

office on November 2 and November 10, 1993, without anything unusual occurring.

7. In October and November, 1993, Dr. Faragher was familiar with accepted techniques for performing therapeutic phlebotomies using collapsible bags or evacuated glass containers.

8. By education, training and experience, Nurse Elyse Bowman was familiar in October and November, 1993, with accepted techniques for performing therapeutic phlebotomies using either collapsible bags or evacuated glass containers.

9. Nurse Elyse Bowman used evacuated glass containers manufactured by Abbott Laboratories in performing Plaintiff's therapeutic phlebotomies on November 2 and November 10, 1993.

10. On November 16, 1993, Nurse Elyse Bowman began performing the third therapeutic phlebotomy on Plaintiff, again using a glass container manufactured by Abbott Laboratories.

11. In performing the phlebotomies on November 2 and November 10 and in attempting to perform the phlebotomy on November 16, 1993, Nurse Elyse Bowman used a blood collection set and glass container manufactured by Abbott Laboratories; the collection set included a thirty-six inch section of clear soft polyvinyl chloride tubing connected to a fifteen-gauge needle at one end which is to be inserted into a vacuum container and a seventeen-gauge needle at the other end that is intended to be inserted into a patient's arm vein; the glass container was

a five hundred milliliter evacuated container that contained a small amount of sterile water. Abbott Laboratories packaged the blood collection set in a box which contained directions for use of the collection set which included: (1) close the tubing with a hemostat or clamp near the bottle needle, and (2) invert and suspend the bottle below the patient's mid-axillary line, and (3) regulate blood flow after making venipuncture by adjusting the clamp or hemostat; however, at least one of the instructions on the collection set was confusing and nonsensical in that it stated: "Insert bottle needle through stopper indentation marked 'X'," but the stopper on the bottle used on November 16, 1993 had no "X."

12. On November 16, 1993, in preparation for the attempted phlebotomy, the Plaintiff was seated in a recliner chair and Nurse Bowman did the following:

    1. She placed the glass collection bottle upright on the floor near Plaintiff;
    2. She cleaned and sterilized Plaintiff's right antecubital area;
    3. She clamped two hemostats on the tubing of the blood collection set, one toward the vein insertion end and the other near the bottle end;
    4. She put a tourniquet or blood pressure cuff on Plaintiff's right arm;
    5. She injected local anesthesia subcutaneously in the area of the anticipated venous puncture;
    6. She inserted the bottle needle into the bottle;
    7. Then she inserted the patient needle into the Plaintiff's vein.

13. After Nurse Bowman inserted the patient needle into the Plaintiff's vein, blood from Plaintiff's vein entered the tubing and extended down the tubing

approximately six to eight inches from the patient needle.

14. Nurse Bowman then removed the two hemostats.

15. Nurse Bowman did not invert and suspend the container below the Plaintiff's mid-axillary line; Nurse Bowman did not regulate the flow of blood before completely releasing the hemostats; Nurse Bowman did not use a single clamp on the tube near the bottle end; Nurse Bowman inserted the patient needle into the Plaintiff's vein before inserting the bottle needle into the bottle stopper.

16. Although Nurse Bowman did not follow all directions for use published by Abbott Laboratories, the manner in which Nurse Bowman set up and used the Abbott Laboratories blood collection set and evacuated glass bottle container was in accordance with acceptable medical standards.

17. Neither Dr. Faragher, Nurse Bowman nor Plaintiff used the blood collection set or the glass container during the attempted phlebotomy on November 16, 1993, in an inappropriate manner.

18. Dr. Faragher and Nurse Bowman followed an appropriate protocol in the manner in which they used blood collection sets and glass collection containers manufactured by Abbott Laboratories and they would have followed that same protocol regardless of differing directions for use or warnings of risks that Abbott Laboratories might have included on a label on the set or container.

19. Immediately after the hemostats were removed, both Plaintiff and Nurse Bowman heard a slushing or gurgling or sucking sound.

20. Immediately after hearing the sound, both Plaintiff and Nurse Bowman observed

the column of blood in the tubing reverse and go back into the Plaintiff's vein, and Plaintiff also observed air mixed with the blood go back into his arm.

21. Immediately thereafter, Plaintiff felt a strange sensation in his right arm above the needle and a sharp pain on the left side of his chest above his heart and began feeling lightheaded.

22. Within a few seconds thereafter, Plaintiff experienced severe chest pain and numbness in and an inability to move his left arm, left fingers and left leg.

23. After seeing the reversal of the blood column and the blood going back into the Plaintiff's arm, Nurse Bowman manually pinched or constricted the tubing with her fingers and called for Dr. Faragher.

24. After Dr. Faragher entered the room, Nurse Bowman explained what she had heard and observed and Dr. Faragher instructed Nurse Bowman to remove the needle from the vein, which Nurse Bowman then did without releasing the tourniquet or blood pressure cuff.

25. After removing the needle from the vein, Nurse Bowman released her manual pinch or constriction of the tubing whereupon blood spurted out of the needle onto the Plaintiff and furniture.

26. Nurse Bowman then inserted the vein needle through the bottle stopper into the glass bottle.

27. Nurse Bowman then took Plaintiff's blood pressure which was 150/90 and Plaintiff's pulse which was 90; just before attempting the phlebotomy, Nurse Bowman had measured Plaintiff's blood pressure at 138/80 and Plaintiff's pulse at

80.

28. Dr. Faragher then performed a neurological examination and determined that Plaintiff's left side was distinctly weaker and had a decreased sensation to touch compared to Plaintiff's right side and concluded that Plaintiff suffered from an air embolism to the right hemisphere of his brain resulting in a stroke.

29. Dr. Faragher and Nurse Bowman did not breach the applicable standard of care by failing to position the Plaintiff in the left lateral Trendelenburg position or by failing to administer oxygen immediately after observing the Plaintiff's symptoms and reaction to blood and air entering his vein from the tubing.

30. Plaintiff was transported from Dr. Faragher's office to a hospital where he was treated by William Clem, MD, a hyperbaric medicine specialist, who performed a neurological examination and treated Plaintiff with hyperbaric oxygen in the hospital's hyperbaric chamber.

31. Dr. Clem diagnosed Plaintiff as suffering from a cerebral air embolism which was the cause of Plaintiff's neurological symptoms of left side weakness and numbness.

32. At the time of the attempted phlebotomy on November 16, 1993, Plaintiff experienced a cerebral air embolism as the result of air entering Plaintiff's venous system and crossing to Plaintiff's arterial circulation through a shunt which was either a patent foramen ovale in Plaintiff's heart or a pulmonary shunt in Plaintiff's lungs or as the result of a profound amount of air overwhelming the pulmonary filtration capability of the lungs.

33. Plaintiff suffered a stroke or a stroke-like event from the cerebral air embolism that

caused damage in the right subcortical region of Plaintiff's brain in an area in the deep white matter of the right hemisphere of the Plaintiff's brain that acts as a connecting point for all four of the cerebral hemispheres – frontal, temporal, occipital and parietal.

34. The cause of the symptoms that Plaintiff experienced immediately after the blood and air entered his venous system was not a transient ischemic attack.

35. Plaintiff's acute symptoms improved with the use of hyperbaric oxygen, but Plaintiff did not fully recover.

36. Plaintiff suffered permanent brain damage from the cerebral air embolism resulting in various injuries that have improved, somewhat, over time since November, 1993, but which to some extent will always remain; Plaintiff has experienced and continues to have persistent left-sided weakness of both the upper and lower extremities, a left foot drop that results in Plaintiff dragging his left toe when walking, a left-sided hemiparesis, impaired cognitive function, and loss of concentration, attention, emotional control and musical ability; these injuries and deficits may continue to improve, but the Plaintiff will never fully recover.

37. Prior to November 16, 1993, Plaintiff had a long history of heavy cigarette smoking, heavy alcohol consumption, elevated cholesterol level, and obesity, but none of this contributed to causing the stroke that Plaintiff experienced on November 16, 1993 or the subsequent medical and related problems resulting from the stroke.

38. Plaintiff experienced a number of medical problems during his lifetime prior to

November 16, 1993, such as head injuries on several occasions when young, gastrointestinal problems, orthopedic problems, arthritic problems, and hemochromatosis, none of which contributed to cause the stroke Plaintiff experienced on November 16, 1993, or the subsequent medical problems associated with the stroke.

39. Since November 16, 1993, because of Plaintiff's problem with spatial memory and attention, it no longer was safe for him to drive eighteen-wheel trucks, the work he had performed for many years; because of his medical problems resulting from the stroke on November 16, 1993, Plaintiff has been disabled and unable to work in gainful employment; Plaintiff has been unable to work as a commercial truck driver.

40. Plaintiff intended to work until retirement between the ages of sixty-five and sixty-seven; because of the stroke Plaintiff lost expected earnings and fringe benefits for a work life expectancy of four additional years.

41. As of November 16, 1993 Plaintiff's life expectancy was 17.2 years.

42. Since November 16, 1993, Plaintiff has experienced and will continue to experience emotional distress because of the numerous physical and emotional problems resulting from his stroke.

43. Although Plaintiff has been unable to work in gainful employment since November 16, 1993, he has been able to drive a motor vehicle and do other activities in a fairly normal manner.

44. The glass container manufactured by Abbott Laboratories that was used in the

attempted phlebotomy on the Plaintiff on November 16, 1993 was a five hundred milliliter glass container from Abbott Laboratories' Lot #72-330-DM-06; a label on the glass container stated that its intended use included blood collection, and that its expiration date was January 1, 1995. The components of the glass container included (1) a glass bottle that could hold slightly more than five hundred milliliters of liquid, and (2) a plastic bail band approximately one-half inch from the bottom of the container to be used to suspend the container in an inverted configuration, and (3) a black hard rubber stopper to be inserted into the mouth of the container, and (4) a thin circular aluminum disk over the top of the black rubber stopper, and (5) a circular aluminum overseal at the top of the container, and (6) two to six milliliters of sterile water solution inside the glass container, and (7) a label on the exterior of the container.

45. The container was manufactured on December 18, 1992, at the Abbott Laboratories' plant in Rocky Mount, North Carolina.

46. From 1980 through 1992, Abbott Laboratories manufactured over five million containers substantially similar to the container used in the attempted phlebotomy on November 16, 1993.

47. Abbott Laboratories manufactured one hundred three thousand one hundred four (103,104) five-hundred milliliter containers in Lot #72-330-DM-06 and two hundred forty (240) of those containers were subjected to random vacuum testing at Abbott Laboratories' Rocky Mount, North Carolina plant and each of the two hundred forty tested containers had a vacuum exceeding Abbott Laboratories'

standard of at least twenty-five inches of mercury.

48. The Abbott Laboratories glass container used in the attempted phlebotomy on November 16, 1993 was packaged by Abbott Laboratories in a box that held twelve containers; six containers from that box were tested after November 16, 1993 and each of the six had an adequate vacuum; three other containers from the box had been used in phlebotomies prior to November 16, 1993 without adverse consequences.

49. Abbott Laboratories' manufacturing process included introducing a vacuum into a glass container with a vacuumizer and sealing the vacuum with a rubber stopper covered with an aluminum cap and overseal, all of which is intended to produce an airtight seal of the vacuum in the bottle.

50. Abbott Laboratories used military standards for statistical sampling of its vacuumized bottles at the Rocky Mount, North Carolina plant; this type of statistical sampling has a failure rate of a statistical nature, but Abbott Laboratories' Director of Quality Assurance Services was unaware of the rate of error for this type of statistical testing.

51. During the history of its manufacture of vacuumized containers at the Rocky Mount, North Carolina, some bottles randomly selected for testing did not meet vacuum specifications.

52. Prior to November 16, 1993, Nurse Bowman who had been using Abbott Laboratory five-hundred milliliter glass containers had experienced situations in which there was an insufficient vacuum to draw more than two-hundred fifty

milliliters of blood when a phlebotomy of five-hundred milliliters was planned.

53. The random selection of two hundred forty bottles out of the total of one hundred three thousand one hundred four in Lot #72-330-DM-06 was insufficient to insure that the bottle used in Plaintiff's attempted phlebotomy on November 16, 1993 had an appropriate vacuum.

54. Between 1986 and September 1993, Abbott Laboratories had received twenty-five customer complaints regarding inadequate or absent vacuums in its five-hundred milliliter glass containers; there were two complaints, concerning fourteen separate bottles, in Lot #72-330-DM-06 about low or no vacuum in containers in that lot.

55. The bottle used in the attempted phlebotomy on November 16, 1993 was manufactured in Rocky Mount, North Carolina at an elevation of only one hundred ten (110) to one hundred thirty (130) feet above sea level; the elevation in Denver, Colorado where the bottle was used on November 16, 1993 was higher than five thousand two hundred feet above sea level.

56. It was not possible to determine, from visual inspection, whether the Abbott Laboratories' bottle used in the attempted phlebotomy on November 16, 1993 had a vacuum; there was no way to determine whether there was a vacuum in the container without breaching the seal.

57. A different manufacturer, McGraw, Inc., manufactures five hundred milliliter empty evacuated containers used for phlebotomies; the McGraw containers are manufactured so that a person can determine by visual inspection whether the container has a vacuum without breaching the seal and is designed so that the

McGraw container is incapable of developing or maintaining a positive pressure relative to surrounding atmospheric pressure.

58. There was physical evidence in the nature of a dent in the aluminum overseal of the Abbott Laboratories' bottle used during the attempted phlebotomy on November 16, 1993 suggesting that the bottle may have sustained trauma during the manufacturing process.

59. The Abbott Laboratories' glass bottle container used in the attempted phlebotomy on November 16, 1993, most likely was sealed during the manufacturing process with neither a vacuum nor a positive pressure, but instead, the bottle was sealed at the atmospheric pressure of Rocky Mount, North Carolina on the date of manufacture.

60. When the sealed Abbott Laboratories' bottle used in the November 16, 1993, attempted phlebotomy was delivered from Rocky Mount, North Carolina, the place of manufacture and sealing, to Denver, Colorado, the place of the attempted phlebotomy, the change in altitude resulted in the bottle developing a positive pressure relative to the atmospheric pressure at Denver, Colorado. The barometric pressure at five thousand two hundred feet in Denver, Colorado is significantly lower than the barometric pressure at one hundred ten to one hundred thirty feet in Rocky Mount, North Carolina; the difference in barometric pressure would be at least one hundred sixteen millimeters of mercury and may be considerably greater.

61. On November 16, 1993, after Nurse Bowman applied the blood pressure cuff or tourniquet the venous pressure in Plaintiff's arm distal of the constriction was sixty

to eighty millimeters of mercury (Hg) above the surrounding atmospheric pressure.

62. The positive pressure in the sealed bottle used in the November 16, 1993, attempted phlebotomy was sufficient to overcome the venous pressure in the Plaintiff's arm at the time of the attempted phlebotomy after the hemostats (clamps) were removed from the tubing.

63. The pressure gradient that existed on November 16, 1993, at the time Nurse Bowman removed the hemostats (clamps) caused the flow of blood extending down the tube of the blood collection set to reverse and caused blood mixed with air to enter Plaintiff's venous system.

64. After the blood collection set needle was removed from Plaintiff's vein and Plaintiff was taken to the hospital, the tubing and the glass container both had some bloody fluid in them; however, the bloody fluid could have found its way into the tube and the glass container for several reasons other than a vacuum in the bottle, which did not exist.

65. The Abbott Laboratories' glass container used in the attempted phlebotomy on November 16, 1993, was designed in a manner that it could develop and maintain positive pressure relative to surrounding atmospheric pressure.

66. The Abbott Laboratories' glass container used in the attempted phlebotomy on November 16, 1993, was designed in a manner that a person using it could not determine from inspection prior to using the glass container whether it did or did not have a vacuum or a positive pressure.

67. The glass container used in the attempted phlebotomy on November 16, 1993,

presented an unreasonable risk of injury to the Plaintiff because it had been designed in a manner that permitted the bottle to develop and maintain positive pressure relative to surrounding atmospheric pressure that could not leak out through the rubber stopper that sealed the bottle whenever a positive pressure developed within the bottle.

68. The glass container used in the attempted phlebotomy on November 16, 1993, presented an unreasonable risk of injury to the Plaintiff because it was designed in a manner that neither the Plaintiff nor Nurse Bowman nor Dr. Faragher could determine from inspecting the glass container prior to using it whether it did or did not have a vacuum or a positive pressure.

69. As of November 16, 1993, Abbott Laboratories could have reasonably expected Dr. Faragher, Nurse Bowman, and the Plaintiff to use the glass container in the phlebotomy procedure.

70. As of November 16, 1993, Abbott Laboratories was aware that if one of the glass containers it manufactured was used in blood collection in a phlebotomy procedure, the glass container would present an unreasonable risk of injury if the container had a positive pressure.

71. As of December 18, 1992, the date Abbott Laboratories manufactured the glass container used in the attempted phlebotomy on November 16, 1993, Abbott Laboratories could have easily designed the container with venting so that it could not develop and maintain a positive pressure without seriously impairing the usefulness of the product or making it unduly expensive to manufacture.

72. As of December 18, 1992, when Abbott Laboratories manufactured the glass container used in the attempted phlebotomy on November 16, 1993, Abbott Laboratories could have designed the stopper on the bottle in such a way that a person could tell from inspecting it whether the container did or did not have a vacuum or a positive pressure without seriously impairing the usefulness of the product or making it unduly expensive to manufacture.

73. As of December 18, 1992, although there was some medical literature dating back several decades describing an air embolism as a complication of a therapeutic phlebotomy into non-vented rigid containers, that literature was not sufficiently specific or definite or widely published to require Abbott Laboratories, in the exercise of ordinary care, to manufacture only vented containers or stoppers that would disclose on inspection whether the container did or did not have a vacuum or positive pressure; other evidence was insufficient to prove that Abbott Laboratories failed to use ordinary care in the conduct of its business of designing, manufacturing, and placing on the market blood collection sets and 500 milliliter glass collection bottles.

74. As a result of the injuries he sustained from the air embolism experienced on November 16, 1993, Plaintiff lost expected earnings over his remaining work life in the amount of $212,000.00 plus fringe benefits in the approximate amount of twenty percent of his gross income loss.

75. As a result of Plaintiff's injuries from the air embolism on November 16, 1993, Plaintiff sustained damages in the nature of loss of future earnings, medical

expenses, loss of ability to provide household services, physical weakness, inability to walk normally, slight left-sided paralysis, impaired cognitive function, inability to concentrate, loss of emotional control, loss of musical ability, and significant emotional distress.

76. The total monetary value of all of Plaintiff's past and future damages resulting from the air embolism and stroke experienced by the Plaintiff on November 16, 1993 is $850,000.00.

**Conclusions of Law**

1. This court has jurisdiction under 28 U.S.C. § 1332 because the Plaintiff and Abbott Laboratories are citizens of different states and the amount in controversy exceeds $75,000.00.

2. The Abbott Laboratories' glass container used in the attempted phlebotomy on November 16, 1993, was placed on the market in a defective condition by Abbott Laboratories because it was designed in a manner that it could develop and maintain a positive pressure relative to surrounding atmospheric pressure thereby creating an unreasonable risk of injury to the Plaintiff.

3. The Abbott Laboratories' glass container used in the attempted phlebotomy on November 16, 1993 was placed on the market in a defective condition in that it was designed by Abbott Laboratories in a manner that a person could not determine from inspection prior to using the glass container whether it did or did not have a vacuum or a positive pressure thereby creating an unreasonable risk of injury to the Plaintiff.

4. Plaintiff Donald Pruitt experienced harm and sustained damages that were proximately caused by the unreasonable risk of injury resulting from the two design defects in the glass container used in the attempted phlebotomy on November 16, 1993.

5. Defendant Abbott Laboratories is liable to Plaintiff Donald Pruitt under the legal principle of strict products liability for damages in the amount of $850,000.00.

6. Plaintiff failed to prove by a preponderance of the evidence that Abbott Laboratories was negligent in the design or manufacture of the blood collection set or glass collection container used in the attempted phlebotomy on November 16, 1993.

7. Plaintiff failed to prove by a preponderance of the evidence that Defendant Abbott Laboratories was negligent in failing to provide adequate directions for use or to warn of dangers of the blood collection set and glass collection container used in the attempted phlebotomy on November 16, 1993.

8. Plaintiff failed to prove by a preponderance of the evidence that any failure to provide adequate directions for use or warnings of risk of harm in regard to the blood collection set and glass collection container presented an unreasonable risk of injury to the Plaintiff.

9. A preponderance of the evidence did not establish that David C. Faragher, M.D. breached a standard of care in his treatment of Plaintiff Donald Pruitt on November 16, 1993, or at any other time.

10. A preponderance of the evidence did not establish that Nurse Elyse Bowman

breached a standard of care in attempting to perform a therapeutic phlebotomy on the Plaintiff on November 16, 1993, or at any other time.

11. A preponderance of the evidence did not establish that there was a misuse of the blood collection set and the 500 milliliter glass collection container during the attempted phlebotomy on November 16, 1993.

UNITED STATES DISTRICT JUDGE